

### **Remarks**

Claims 1-20, 25, 50, 77, 102 were previously canceled without prejudice or disclaimer. Claims 125 and 126 have been canceled herein without prejudice or disclaimer. Upon entry of the present amendments, claims 21-24, 26-49, 51-76, 78-101, and 103-124 will be pending.

#### ***Claims Under Consideration***

Applicants note that the claims listed as pending, withdrawn, and rejected in items #4 and #6 on the pending Office Action Summary page differs from the list of claims specified as under examination on page 2, second paragraph, and throughout the pending Office Action. *See*, Paper No. 24. Applicants understand the list of claims specified as under examination on page 2, second paragraph, to be the correct list; except for recitation of claim 102 which was previously canceled without prejudice or disclaimer. *See*, Response Under 37 C.F.R. § 1.116, page 1, submitted Dec. 13, 2002. Thus, Applicants understand the correct list of claims currently under examination to be 21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-101, 103-115, and 124-126. Clarification is requested.

#### ***Claim Rejections Under 35 U.S.C. § 112***

Claims 21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-101, 103-115, and 124 were rejected under 35 U.S.C. § 112 as allegedly lacking enablement. In particular, the Examiner argued that mRNA expression levels are not reliable indicators of protein expression levels, and cited example references in support of this contention. The Examiner concluded: “[T]he enablement of the claimed invention appears to be predicated on the differential expression of SEQ ID NO:2 in tumor cells compared with normal controls. Applicant has presented no evidence that demonstrates that this is in fact the case.” *See*, Paper No. 24, page 3, lines 18-21.

Applicants respectfully submit herewith evidence that demonstrates differential expression of Colon Specific Protein (a.k.a., RegIV) in tumor cells compared with normal controls. In particular, Applicants submit a Declaration by Senior Scientist Dr. Adam Bell describing the results of immunoblot analysis performed with antibodies generated against the polypeptide of Colon Specific Protein (a.k.a., RegIV). Applicants also submit a copy of an

immunoblot as Exhibit A. The immunoblot demonstrates significantly higher levels of Colon Specific Protein expression in colon and rectal tumor tissue compared to normal colon and rectal tissue. Therefore, Applicants respectfully submit that the Examiner's request for objective evidence corroborating the specification's description of upregulated Colon Specific Protein expression in colon cancer has been met herewith. Accordingly, Applicants respectfully request the rejection of claims 21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-101, 103-115, and 124-126 under 35 U.S.C. § 112 be withdrawn.

***Claim Rejections Under 35 U.S.C. § 101***

The Examiner has also issued a new ground of rejection of claims 21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-101, 103-115, and 124 under 35 U.S.C. § 101. *See*, Paper No. 24, page 6, item 7. Following the rationale provided in support of this rejection the Examiner concluded: "The rejection can be obviated by submission of objective evidence demonstrating that SEQ ID NO:2 is differentially expressed in primary colon cancer compared with normal colon cells." *See*, Paper No. 24, page 10, first paragraph, last sentence.

Accordingly, Applicants submit that the objective evidence described above and submitted herewith complies with the Examiner's suggestion. Therefore, Applicants submit that the rejection of claims 21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-101, 103-115, and 124 under 35 U.S.C. § 101 has been obviated. Withdrawal of the rejection is respectfully requested.

***Claim Rejections Under 35 U.S.C. § 112***

The Examiner has also rejected claims 21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-101, 103-115, and 124 under 35 U.S.C. § 112 based on the above cited rejection under 35 U.S.C. § 101. Again, the Examiner concluded: "The rejection can be obviated by submission of objective evidence demonstrating that SEQ ID NO:2 is differentially expressed in primary colon cancer compared with normal colon cells." *See*, Paper No. 24, page 10, item 8.

Again, Applicants submit that the objective evidence described above and submitted herewith complies with the Examiner's suggestion. Therefore, Applicants submit that the rejection of claims 21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-101, 103-115, and 124 under 35 U.S.C. § 112 based on the rejection under 35 U.S.C. § 101 has been obviated. Withdrawal of the rejection is respectfully requested.

The Examiner also rejected claims 125 and 126 under 35 U.S.C. § 112 as allegedly lacking written description. *See*, Paper No. 24, page 10, item 9. Applicants have herein canceled claims 125 and 126 without prejudice or disclaimer. Therefore, the rejection of claims 125 and 126 has been rendered moot.

### ***Claims Withdrawn From Consideration***

Method claims 38-45, 64-71, 90-97, and 116-123 were previously withdrawn from consideration by the Examiner as being drawn to a non-elected invention. *See*, Paper No. 12, Page 2, item 2 (mailed March 4, 2002). Applicants respectfully request rejoinder of these claims in light of the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996). In view of these Federal Circuit decisions a notice was published in the Official Gazette which set forth new guidelines for the treatment of product and process claims. *See* 1184 OG 86 (March 26, 1996). Specifically, the notice states that:

[I]n the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim.

*Id.* Accordingly, upon finding antibody claims to be allowable, Applicants respectfully request that method claims 38-45, 64-71, 90-97, and 116-123 which depend therefrom be rejoined and examined for patentability. *See* also M.P.E.P. § 821.04.

### ***Conclusion***

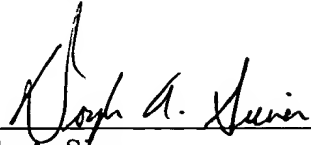
Applicants respectfully request that the above-made amendments and remarks be entered and made of record in the file history of the instant application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37

C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

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Respectfully submitted,

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